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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CASE NO. 18-CR-00258 EJD STIPULATION AND [PROPOSED] FOURTH SUPPLEMENTAL PROTECTIVE ORDER REGARDING FDA DOCUMENTS

The United States of America, by and through ADAM A. REEVES, Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. § 515, and JEFF SCHENK, JOHN C. BOSTIC, and ROBERT S. LEACH, Assistant United States Attorneys for the Northern District of California, and the defendants, ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, and their attorneys, KEVIN DOWNEY and LANCE WADE of Williams & Connolly for HOLMES, and JEFFREY B. COOPERSMITH and STEPHEN A. CAZARES of Orrick Herrington & Sutcliffe for BALWANI, hereby stipulate and jointly request that the Court issue a fourth supplemental Protective Order in this

case as described below.

The parties stipulated to, and the Court entered, a Protective Order in this case on or about July 2, 2018 (Docket #28). A Stipulation and Supplemental Protective Order was entered by the Court on July 17, 2019 (Docket #90). On July 31, 2019, the Court entered a Stipulation and Second Supplemental Protective Order (Docket #117) and on September 17, 2019, the Court entered a Stipulation and Third Supplemental Protective Order Regarding FDA and CMS Documents (Docket #120).

On November 5, 2019, the Court issued an Order Granting Motion to Compel production of six categories of documents held by FDA and CMS (Docket #174). The Court further found "the Prosecution has knowledge of and access to the at-issue documents" and "order[ed] the Prosecution to produce the documents discussed below as part of their Rule 16 obligation, and to assist the Agencies however possible to ensure the timely production of documents." *Id.* at 3.

In order to facilitate review and production of the FDA documents responsive to the Motion to Compel, on December 1, 2019, the parties jointly moved the Court for an order requiring FDA to produce documents obtained using the ordered and agreed-upon collection terms to DOJ notwithstanding the provisions of 21 U.S.C. §§ 331(j) and 360j(c), which FDA asserted would have prohibited FDA from turning over unreviewed documents to DOJ (Docket #183). At that time, the parties noted that they would be jointly moving to amend or supplement the protective orders in this case to address the appropriate handling and review of the FDA documents to be produced by DOJ to Defendants in this case. *Id.* The Court entered the Stipulation and Order Regarding Certain FDA Documents on December 2, 2019 (Docket #184).

Accordingly, in order to facilitate the production of responsive FDA documents by DOJ to the Defendants, the parties stipulate and agree to a Court order as follows:

1. All FDA documents and information produced by DOJ in response to the Motion to Compel after November 5, 2019, shall be referred to herein as "Confidential FDA Materials" and shall include a header or footer with the words "ATTORNEYS' EYES ONLY FDA MATERIALS -- SUBJECT TO FOURTH SUPPLEMENTAL PROTECTIVE ORDER."

2. In order to protect from disclosure any non-Theranos trade secret or confidential commercial information (hereafter, "third-party TS/CCI") contained within the Confidential FDA Materials, facilitating compliance with the Order Granting Motion to Compel, DOJ will disclose the Confidential FDA Materials to defendants' defense team (as defined below in subsection (a)) in accordance with the following limitations on the use of and access to the Confidential FDA Materials.

a. For purposes of this Fourth Supplemental Protective Order, the term "defense team" refers to (1) each Defendant's counsel of record; (2) other attorneys on Defendants' defense team who may be consulted regarding case strategy in the above-captioned matter; and (3) paralegals, legal assistants, support staff, contract attorneys, and document review platform vendors assisting Defendants' counsel of record on this case, provided that all individuals included in categories (2)-(3) have been advised of their obligations under this Fourth Supplemental Protective Order and have affirmed to Defendants' counsel of record that they agree to be bound by the terms of this Fourth Supplemental Protective Order. The term "defense team" does not include Defendants, their family members, or their agents not assisting Defendants' counsel of record in this case, nor does it include expert witnesses or consultants.

b. Defendants' counsel of record shall advise all members of their respective defense teams of the defense team members' obligations under this Fourth Supplemental Protective Order and ensure the defense team members' agreement to follow this Fourth Supplemental Protective Order, prior to providing any defense team members with access to Confidential FDA Materials.

c. Before any Defendant, expert witness, or consultant (collectively, "Non-Counsel") may review Confidential FDA Materials in this case, Defendant's defense team must review each document to be shown to Non-Counsel and determine whether it contains any third-party TS/CCI. If the Defendant's defense team determines in good faith that the document does not contain any third-party TS/CCI, it may be shown to Non-Counsel and Non-Counsel must comply with the terms of this Fourth Supplemental Protective Order, including this paragraph. If the document contains any third-party TS/CCI, it may not be shown to any Non-Counsel until the defense team provides the document to FDA for expedited review by personnel not involved at any time with witness preparation in the DOJ or

SEC cases (*SEC v. Balwani*, 18-cv-01603 (N.D. Cal.)) (hereinafter "FDA Review Personnel") for redaction of all third-party TS/CCI and receives the document back with redactions or the agency notifies Defendants' counsel that no redactions are needed. "Expedited review" means that FDA will respond to Defendants' counsel regarding potential redactions for third-party TS/CCI within five days per every 350 pages, not including weekends or federal holidays. Defendants' counsel of record may challenge any agency decision regarding redactions by bringing a motion before the Court. FDA Review Personnel may not identify or communicate the substance of any document presented by the defense for TS/CCI review to any custodian whose files are the subject of the FDA's document collection efforts (except for David Mednick, the supervising attorney for disclosure at FDA's Office of Chief Counsel), any attorney representing FDA in the instant case, the SEC case, and the underlying investigations, or anyone at the Department of Justice, FBI, United States Postal Inspection Service, SEC, and FDA's Office of Criminal Investigations. For purposes of clarity, FDA Review Personnel will not disclose the documents or identifying information about the documents to, or otherwise discuss such documents with, anyone involved with witness preparation in the DOJ or SEC cases. Once Non-Counsel may review a document, Non-Counsel may only review it (1) in the presence of that Defendant's counsel of record or another member of the defense team, or (2) via an electronic document review platform utilized and controlled by Defendants' counsel. Non-Counsel may not take any Confidential FDA Materials out of the room where they are meeting with the defense team and, if Non-Counsel is reviewing the documents via electronic document review platform, the documents may not be photographed, printed, copied, or reproduced in any manner. Non-Counsel may not write down or memorialize any information contained in the Confidential FDA Materials, except in direct communications with members of Defendant's defense team which communications to or from Non-Counsel may include a copy of Confidential FDA Materials For purposes of clarity, once Non-Counsel may review a document, Non-Counsel may attach Confidential FDA Materials to emails sent directly to members of Defendant's defense team, and members of Defendant's defense team may attach Confidential FDA Materials to emails sent directly to Non-Counsel. Non-Counsel shall not forward or copy any such email to anyone other than a member of Defendant's defense team. Non-Counsel may

not utilize any information obtained by review of the Confidential FDA Materials for any purpose other than assisting in the defense of this case and the parallel SEC case for Mr. Balwani.

d. The defense teams shall not permit anyone other than the defense teams to have possession of Confidential FDA Materials, including any Non-Counsel unless permitted under Paragraph 2(c).

f. The defense teams and Non-Counsel (when permitted under Paragraph 2(c)) shall maintain Confidential FDA Materials safely and securely, and shall exercise reasonable care in ensuring the confidentiality of those materials by (1) not permitting anyone other than defense team members and Non-Counsel (when permitted under Paragraph 2(c)) to see Confidential FDA Materials; (2) not divulging to anyone other than the defense teams and Non-Counsel (when permitted under Paragraph 2(c)) the contents of Confidential FDA Materials; and (3) not permitting Confidential FDA Materials to be outside the defense teams' offices, secure electronic document review platforms and electronic devices utilized for such review, homes, vehicles, or personal presence.

g. To the extent that notes, including emails, are made that memorialize, in whole or in part, the information in any Confidential FDA Materials, or to the extent that copies are made for authorized use by members of the defense teams or Non-Counsel (when permitted under Paragraph 2(c)), such notes, copies, or reproductions become Confidential FDA Materials subject to this Fourth Supplemental Protective Order and must be handled in accordance with the terms of this Fourth Supplemental Protective Order.

h. The defense teams and Non-Counsel (when permitted under Paragraph 2(c)), shall use Confidential FDA Materials only for the litigation of this matter and, for Mr. Balwani, the SEC case and for no other purpose. Litigation of this matter includes any appeal filed by a Defendant in this case or, for Mr. Balwani, the SEC case, and any motion filed by a Defendant pursuant to 28 U.S.C. § 2255 relating to the DOJ case.

i. Before any party files Confidential FDA Materials with the Court or divulges the contents of such materials in court filings, the party shall first consult with FDA Review Personnel to ensure that the document is properly redacted for public filing. Such FDA Review Personnel shall

respond to any inquiry by Defendants regarding redactions for public filing within five days per every 350 pages, not including weekends or federal holidays. The parties further agree to meet and confer with FDA in advance of trial regarding appropriate procedures for the use of Confidential FDA Materials at trial.

j. Any Confidential FDA Materials disclosed after the November 5, 2019 Order Granting Motion to Compel shall be subject to the terms of this Fourth Supplemental Protective Order. Willful violation of this Fourth Supplemental Protective Order, or any court order, by the parties, defense counsel or Defendants' agents, and Non-Counsel, can subject the violator to sanctions for contempt of court.

k. Upon the final disposition of this case and, for Mr. Balwani, the SEC case – i.e., after the conclusion of the latter of any acquittal or not guilty verdict, and post-conviction or post-guilty verdict proceeding, any settlement, or any appeal, any Confidential FDA Materials shall not be used, in any way, in any other matter, inconsistent with this Fourth Supplemental Protective Order absent a court order. All Confidential FDA Materials maintained in the defense teams' files shall remain subject to this Fourth Supplemental Protective Order unless and until such order is modified by court order. Within sixty days after final disposition of this case for Ms. Holmes and, for Mr. Balwani, this case and the SEC case, the defense teams shall return the Confidential FDA Materials to the government or certify that the Confidential FDA Materials have been destroyed or deleted from any digital storage, only to the extent that such return to the government or destruction does not violate any professional obligation of defense counsel under the California Rules of Professional Conduct, the California Business and Professions Code, or any other rule of professional responsibility to maintain client files.

l. In the event that there is a substitution of counsel prior to when such documents must be returned or destroyed, this Fourth Supplemental Protective Order shall be binding on new defense counsel, who then shall (1) become the defense team's custodian of the Confidential FDA Materials; and (2) upon the conclusion of appellate and post-conviction proceedings, become responsible for returning to the government or certifying the destruction of all Confidential FDA Materials.

IT IS SO ORDERED.

DATED: December 23, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
by 28 U.S.C. § 515

/s/
JEFF SCHENK
JOHN C. BOSTIC
ROBERT S. LEACH
VANESSA BAEHR-JONES
Assistant United States Attorneys

DATED: December 23, 2019

/s/
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

/s/
ELIZABETH HOLMES

DATED: December 23, 2019

/s/
JEFFREY B. COOPERSMITH
STEPHEN A. CAZARES

/s/
RAMESH "SUNNY" BALWANI

SO ORDERED.

DATED: _____

_____
HONORABLE EDWARD J. DAVILA
United States District Court Judge